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ANESTHETIC FORMULATION OF TUMESCENT SOLUTIONS

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There is no standard or official recipe for the tumescent anesthetic solutions. The actual concentrations of lidocaine and epinephrine should depend on the areas to be treated and clinical situation. In this article the word *dosage* implies the total amount of a drug given relative to the patient's weight in kilograms (mg/kg); a *dose* is a quantity of a medicine given at one time measured in milligrams (mg).

The following important concepts and warnings must be emphasized in order to minimize the risks of lidocaine toxicity. Safe dosages of tumescent (very dilute) lidocaine and epinephrine are not the same for "out-of-the-bottle" commercial (considerably more concentrated) lidocaine. Whereas the safe maximum dosage of tumescent lidocaine (with epinephrine) at concentrations of between 0.05% and 0.1% is between 45 mg/kg to 50 mg/kg, the traditional dosage limitation for commercial lidocaine (with epinephrine) at concentrations of 0.5%, 1%, or 2% remains valid at 7 mg/kg. All physicians should be extremely careful to recognize this vital distinction.

MAXIMUM SAFE DOSAGE

The recommended maximum dosage of lidocaine is 45 mg/kg in relatively thin patients and 50 mg/kg for obese patients. I avoid using more than 55 mg/kg of lidocaine. At dosages of 50 mg/kg to 55 mg/kg of tumescent lidocaine there are occasional patients who experience nausea and vomiting approximately 12 hours after the tumescent infiltration; in these patients, whenever the plasma lidocaine concentration has been measured, it has never exceeded of 3.5 μg/ml. To minimize the risk of this worrisome symptom, it is preferable not to exceed 45 mg/kg of tumescent lidocaine. Furthermore, the surgeon must not forget that these dosage limitations assume that there are no drug interactions and no unimpaired function of hepatic cytochrome P450 3A4.

Signed Written Orders

It is absolutely essential that the surgeon provide explicit written orders for the formulation of the tumescent local anesthetic solution. It should be standard policy that no solutions are to be mixed unless the surgeon has signed the orders and the orders are on the patient's chart. All orders for tumescent anesthesia should include documentation of the patient's weight in kilograms, the maximum desired dosage expressed in milligrams per kilogram (mg/kg), and the exact amount of each drug to be included in the tumescent

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solution expressed in milligrams per liter (mg/L) or milliequivalents per liter (mEq/L).

Know the Correct Dosage to Give

The surgeon, anesthesiologist, and nurses must always be aware of the patient's final total milligram dose (mg) and the milligram per kilogram dosage (mg/kg). For each patient, the surgeon's orders must also explicitly state the surgeon's determination of the maximum safe dosage of tumescent lidocaine in terms of milligram of lidocaine per kilogram of patient weight (mg/kg). I am aware of at least 3 cases where surgeons were charged, but not convicted, with criminal negligence because of apparent errors in lidocaine dosing.

Specify the Dosage in Terms of Milligrams

The orders for formulating the solution of local anesthesia for the tumescent technique should specify the exact total milligrams of lidocaine and epinephrine, and the milliequivalents of sodium bicarbonate per liter of tumescent solvent (mg/L and mEq/L). The orders should not be given in terms of milliliters of 1% lidocaine per liter of solution [(mL/L)(10 mg/mL)]; to do so increases the risk of inadvertent dosing errors. It is much easier to determine the milligram per kilogram (mg/kg) dosage of lidocaine when the concentration of lidocaine in each liter is specified in terms of milligrams per liter (mg/L).

Use Only 1% Lidocaine

It is preferable that a surgeon's formulary only stock 1% lidocaine commercial vials of lidocaine. The risk of an inadvertent overdose is vastly increased when 2% vials of lidocaine are available. I know of more than one incident where a patient received double the intended dose of lidocaine when the order was given in terms of volume of out-of-the-bottle commercial lidocaine and a 2% lidocaine solution was used instead of the intended 1% solution. Although these cases did not result in serious toxicity, each incident of incorrect dosage represents a potential disaster. Epidural anesthesia may require the use of 2% lidocaine, but there are no dermatologic surgical procedures that cannot be accomplished with 1% lidocaine or a more dilute lidocaine solution.

Licenced Medical Personnel Prepare the Solution

It is critical that only well-trained personnel do the actual preparation (i.e., the mixing of the ingredients for the tumescent solution). Surgical operating room technicians or medical assistants are usually not licenced to prepare or administer drugs and anesthetics. Unlicenced personnel are more likely to make errors in the interpretation of anesthetic orders or the actual mixture of the tumescent anesthetic solution. The actual mixing of the tumescent local anesthetic solution requires the immediate "eyes-on or hands-on" supervision of licenced medical personnel.

Preparation at the Time of Surgery

In order to avoid medication errors, it is probably safer to prepare the tumescent anesthetic solution in the operating room at the time of surgery. Preparing the tumescent anesthetic solution in large batches, and far in advance of the individual surgery, may increase the risk of unrecognized contamination or inadvertent dosage errors. Concerns about safety, in particular the avoidance of unanticipated mix-ups, would appear to outweigh the possible convenience of preparing tumescent solutions intended for multiple patients far in advance of the time of surgery. From this perspective, any questions about the "shelf-life" of tumescent anesthetic solutions appear irrelevant.

Save All Empty Lidocaine Bottles

All empty vials of lidocaine and all empty vials of epinephrine should be temporarily saved until the surgical procedure is completed. This precautionary strategy or plan of action will enable anyone to double-check the total lidocaine or epinephrine dosage. If there is a discrepancy between an intended dosage and the number of empty vials of lidocaine or epinephrine then all of the remaining tu-

mescent anesthetic mixtures must be discarded and new mixtures prepared.

Avoid Postoperative Sedatives

The postoperative use of diazepam during the immediate 24 hours after tumescent liposuction is relatively contraindicated. Diazepam or other sedatives may actually increase the risk of lidocaine toxicity by inhibiting cytochrome P450 3A4, or by impairing ventilation and producing respiratory acidosis.

Normal Saline is the Preferred Tumescent Solvent

As discussed below, normal saline (NS), also known as physiologic saline or 0.9% sodium chloride, is the preferred solvent for dilute solutions of local anesthetics intended for delivery by the tumescent technique. There may be an increased risk of intracellular edema associated with LR when the total volume of tumescent solution is excessive, and especially when a tumescent infiltration is accompanied with the administration of IV crystalloid solutions. This is discussed in greater detail later in this article.

Anesthesiologist and Surgeon Share Responsibilities

The safety of a surgical patient is ultimately the responsibility of all physicians, surgeons, and anesthesiologists in the operating room. When an anesthesiologist is providing systemic anesthesia, the anesthesiologist must be completely informed about and concur with the total dosage of tumescent lidocaine. An anesthesiologist who is not cognizant of the lidocaine dosage (mg/kg) nor the volume of subcutaneously infiltrated tumescent fluid may be unable to avoid adverse drug-interactions or systemic fluid overload. When providing anesthesia for tumescent liposuction, any anesthesiologist who is unfamiliar with the pharmacology and pathophysiology of tumescent liposuction is not in compliance with the standards of the American Society of Anesthesiologists.[11]

ASSIDUOUS RECORDS

It is absolutely essential that the surgeon insist that the surgical staff assiduously maintain complete, legible records that document the total milligram dosage and concentration of local anesthetic ingredients in each liter of tumescent solution. The important ingredients include lidocaine, epinephrine, and sodium bicarbonate.

Traditionally, physicians have only used relatively small dosages of subcutaneous local anesthetics. In fact, very few medical students or surgical residents have ever trained to document or record the exact amount of local anesthetic used. Specific and precise preoperative orders for subcutaneous infiltration local anesthesia are rarely recorded. Now with increased use of relatively high dosages of lidocaine employed with tumescent anesthesia, many surgeons continue to have a casual, nonrigorous approach to documentation of local anesthesia dosages.

Sloppy records are dangerous, below the standard of care, and often considered tantamount to malpractice. Careless anesthesia records combined with a patient death may result in a prosecution for criminal negligence. There have been at least two such cases where the surgeon's notes did not accurately or unambiguously document the total dosage of lidocaine; in both cases the patients died after receiving general anesthesia plus tumescent local anesthesia, which was not well documented. One case involved inhalational general anesthesia, and the other propofol. Although both cases resulted in charges of criminal negligence, neither resulted in a conviction. Criminal negligence is not covered by malpractice insurance, and a conviction can involve time in prison.

LIDOCAINE/EPINEPHRINE CONCENTRATIONS

The concentration of lidocaine and epinephrine in an anesthetic solution should vary according to the clinical requirements. There is no "correct" or sanctioned concentration of lidocaine or epinephrine for tumescent local anesthesia. The recommendations in this article with respect to the concentration of tumescent lidocaine for liposuction of various areas of the body has been developed empirically. Years of experience and careful observa-

tion have helped define an estimate of the optimal concentrations. The goal is to determine the minimal concentration for each component of the anesthetic solution that consistently permits painless liposuction. Areas that are especially fibrous, such as the upper abdomen, breast, and back, also tend to be associated with increased surgical bleeding. The more fibrous areas tend to require a higher concentrations of lidocaine and epinephrine. Less fibrous and less sensitive areas require lower concentrations. Recommended concentrations are simply guidelines and are always subject to modification (Table 1).

The use of smaller cannulas is associated with less discomfort and a smaller probability of encountering an area of painful liposuction. Therefore, the use of smaller cannulas allows the use of lower drug concentrations. The use of a careful deliberate surgical technique that initiates liposuction using the smallest cannulas and then increases cannula size sequentially causes less discomfort than beginning liposuction with relatively large cannulas.

If several areas are treated by liposuction on the same day, then the surgeon might be constrained to use the lowest concentrations to avoid exceeding the maximal safe dosage limits (mg/kg).

Epinephrine in Tumescent Anesthetic Formulation

Epinephrine, a hormone derived from the adrenal medulla, is also known as adrenaline. Pharmacologically it acts as both an alpha and a beta agonist. Therefore, epinephrine causes both an increased heart rate, and peripheral vasoconstriction and increased blood pressure. More importantly for tumescent anesthesia, epinephrine is a potent capillary vasoconstrictor that accounts for the dramatic hemostasis associated with the tumescent technique.

Epinephrine and Tachycardia

It is not uncommon for patients to give a history of some type of adverse reaction to epinephrine. Typically this history derives from an unpleasant experience with dental anesthesia in which the patient experienced the predicable pharmacologic effects of rapid systemic absorption. The injection of a drug into the highly vascular oral (periodontal, gingival, or buccal) mucosa is more likely to produce a rapid systemic absorption compared to an injection into less vascular tissue. Rapid absorption is a pharmacologic phenomenon, it is not an allergic reaction. Rapid absorption of epinephrine can be expected to produce a relative tachycardia, tremors, and anxiety. Patients who have experienced tachycardia because of rapid absorption of epinephrine following dental anesthesia do not, in my experience, have a similar reaction with tumescent anesthesia for liposuction.

Liposuction surgeons should be cautious of patients who have a confusing history of an adverse reaction to epinephrine. Patients who are taking pseudoephedrine for nasal decongestion, or who are taking "health-food" supplements that contain ephedrine-like

Table 1. RECOMMENDED CONCENTRATIONS FOR EFFECTIVE TUMESCENT ANESTHESIA FOR LIPOSUCTION

Areas	Lidocaine (mg/L)	Epinephrine (mg/L)	Sodium Bicarbonate (mEq/L)
Basic/Checking	500	0.5	10
Hips	700 to 750	0.65	10
Lateral Thighs	"	"	"
Medial Thighs	"	"	"
Anterior Thighs	"	"	"
Knees	"	"	"
Back	1000	0.65 to 1.0	10
Male Flanks	"	"	"
Arms	"	"	"
Female Abdomen	1000 to 1250	1.0	10
Male Abdomen	1250	1.0	10
Male Breasts	"	"	"
Female Breasts	1500	1.5	10
Chin/Cheek/Jowls	"	"	"
CO_2 Laser Facial Resurfacing	600 mg/250 mL	1 mg/250 mL	5 mEq/250 mL

chemicals are predisposed to epinephrine-associated tachycardias. It is possible that the patient has an undiagnosed primary cardiac arrhythmia, an occult cardiac valvular disease with intermittent tachycardia, or a subclinical metabolic disorder such as hyperthyroidism, carcinoid, or pheochromocytoma. If there is a significant doubt in this regard, then one might consider an internal medicine consultation.

If the patient's history is clearly consistent with a rapid absorption of epinephrine and the consequent pharmacologic response with tachycardia, then tumescent liposuction probably poses a minimal risk. Nevertheless, initially it would be prudent to limit the amount of liposuction to relatively small volumes. Once the first procedure has been completed without evidence of tachycardia, tremor, or an anxiety reaction then one can proceed on a subsequent day with a standard dosage of epinephrine for tumescent anesthesia. The routine use of clonidine, 0.1 mg given preoperatively to patients who do not already have preoperative bradycardia or hypotension, has greatly reduced the incidence of intraoperative and postoperative tachycardia with tumescent local anesthesia.

Regional Variation of Epinephrine Concentration

One can vary the concentration of epinephrine depending on the particular area that is being targeted for tumescent liposuction. In areas that tend to be associated with increased intraoperative bleeding, such as the upper abdomen, the back/flank areas, and especially fibrous areas of fat, it is reasonable to use 1 mg of epinephrine per liter of tumescent anesthetic solution. For other areas, an epinephrine concentration of 0.65 mg of epinephrine per liter is sufficient.

Adverse Drug Interactions with Epinephrine

Beta-blockers and epinephrine are said to pose a potential for an adverse interaction by the selective blocking of the beta-adrenergic receptors and permitting unopposed epinephrine stimulation of alpha-adrenergic receptors. Theoretically the alpha-adrenergic vaso-motor sympathomimetic stimulation will increase peripheral vascular resistance and precipitate hypertensive crisis and its sequelae. There is little doubt that adverse interactions between epinephrine and beta-blockers can cause significant problems. The determining factor seems to be the rate of epinephrine absorption into the systemic circulation.

Rapid absorption of a subcutaneous injection of epinephrine can occur in at least two common clinical settings: when a relatively high concentration of epinephrine (1:1000) is injected subcutaneously to treat a suspected allergic reaction or when epinephrine (1:100,000) is injected into relatively highly vascular tissue such as the buccal mucosa for local anesthesia in dentistry, ocular mucosa with blepharoplasty, or a regional nerve block. A rapid absorption of subcutaneous epinephrine is more likely to result in a toxic reaction than when the epinephrine is absorbed much more slowly.

When epinephrine is injected subcutaneously there is a 5- to 15-minute delay before the onset of maximum cutaneous blanching and vasoconstriction. Therefore, within the first few minutes following a subcutaneous injection, a significant amount of epinephrine can reach the systemic circulation and precipitate an abrupt hypertensive drug interaction with secondary bradycardia. There is a report of six cases where lidocaine and epinephrine was injected subcutaneously for vasoconstriction prior to blepharoplasty (eyelid surgery) and resulted in a rapid onset of malignant hypertension and severe bradycardia.[3] One case concerned a patient who was given 0.3 mg of epinephrine subcutaneously to treat a suspected allergic reaction and rapidly developed hypertension and bradycardia.[4] Another report documented chest pain in four patients on propranolol following a subcutaneous injection of 0.4 to 0.5 mg of epinephrine.[16] There are also reports of severe hypertension in patients taking propranolol following an IV infusion of epinephrine.[5, 9, 12]

In contrast, when epinephrine (1:100,000) is injected subcutaneously into tissue having a relatively low vascularity, absorption is slower and the incidence is greatly reduced if not entirely avoided. A prospective study of patients undergoing Mohs' micrographic surgery for skin cancers by local anesthesia with lidocaine and epinephrine compared 10 patients taking propranolol and 10 patients without propranolol. Although there was no hypertension in either group, the "nonpropranolol group" had a slightly decreased

blood pressure compared to the propranolol group.[2]

Extensive experience with tumescent liposuction and the concomitant use of beta-blockers has revealed no evidence of hypertension. This apparent lack of any adverse interaction between extremely dilute tumescent epinephrine injected subcutaneously in patients taking beta-blocking drugs might be explained by the exceptionally slow absorption of epinephrine delivered by the tumescent technique.

The route of drug delivery and the rate of drug absorption are decisive factors in determining the relative risk of toxicity. With the slow systemic absorption of epinephrine associated with the tumescent technique, the risk of an adverse interaction between epinephrine and beta-blockers is small. Among my patients who were taking beta-blockers, careful blood pressure monitoring has shown no evidence of postoperative hypertension. Nevertheless, this experience is not proof that there is no risk of an adverse interaction of tumescent anesthesia and beta-blockers.

It is often preferable that patients who are being treated with nonselective beta-blockers for hypertension or migraine headaches be maintained on these medications. A cautious approach to such patients is to limit the number of areas that will treated and the total dosage of epinephrine that will given during any single session of tumescent liposuction.

When using a local anesthetic that contains epinephrine, caution is always necessary. In spontaneously hypertensive rats pretreated with a cardioselective beta-blocker there is no problem after an intraperitoneal (IP) dosage of epinephrine; however, pretreatment with a noncardio-selective beta-blocker and IP epinephrine produced systemic vasoconstriction and pulmonary congestion.[7]

SHELF LIFE OF TUMESCENT ANESTHETIC SOLUTION

The United States Food and Drug Administration (FDA) requires that manufactures of 0.9% sodium chloride and LR provide information that states, "When introducing additives, use aseptic techniques. Mix thoroughly. Do not store."

It is safer to prepare the tumescent anesthetic solution on the day of surgery in the operating room. Medicolegal considerations favor the use of anesthetic solutions that are freshly prepared in the operating room immediately before surgery. It would be difficult to defend the use of a "stale" solution in the face of a complication attributable to pharmacologic instability or bacterial contamination.

An error in the preparation of the tumescent anesthetic solution is more easily detected if the anesthetic is mixed immediately before or during the surgery. By saving the empty bottles of lidocaine and empty vials of epinephrine, the total dosage of these drugs can be double-checked simply by counting the empty containers. If tumescent anesthetic solution is prepared a day or more in advance, or outside of the operating room, then an inadvertent overdose of lidocaine might not be detected.

The efficacy of a tumescent anesthetic solution is not maximal when mixed several days in advance of a surgery. The shelf-life varies as a function of pH, temperature, and the concentration of other solutes. In particular, the vasoconstrictive properties of epinephrine are not stable at a pH $\geq$ 5. There is a greater risk that lidocaine might precipitate from an older solution or from a solution with a higher pH. If a liter bag of tumescent anesthetic solution has been prepared days in advance, one cannot always be certain that it has been properly stored.

NEVER ADD SODIUM BICARBONATE TO BUPIVACAINE

Bupivacaine is a larger and less soluble molecule than lidocaine. For example, adding 5 mEq of sodium bicarbonate to 50 mL of bupivacaine (0.75%) will result in the immediate precipitation of the bupivacaine. Injecting such a suspension intradermally or subcutaneously has caused full-thickness dermal necrosis.

TRIAMCINOLONE IS NOT NECESSARY

Once, the addition of triamcinolone (10 mg/L) was considered beneficial in reducing the incidence of focal postliposuction subcutaneous inflammation.[8] In the early days of my experience with tumescent liposuction approximately 2 to 4% of patients would present focally tender pink, warm, sterile subcutaneous nodules that did not respond to antibiotics. When peculiar "postliposuction pannicu-

litis" was treated with a course of oral antibiotics prednisone (10 mg/day), however, the condition would improve dramatically within 24 to 48 hours. By a process of induction, it was concluded that including triamcinolone in the anesthetic solution might prevent "postliposuction panniculitis." In fact, the addition of triamcinolone seemed to reduce the incidence of this focal inflammation.

TUMESCENT SOLVENTS AND FLUID HOMEOSTASIS

The choice of which solvent to add the lidocaine and epinephrine to is an important aspect of the tumescent technique. It seems self-evident that the solvent should be isotonic and the pH nearly physiologic. Within the realm of safe conservative liposuction, there is probably no significant difference between NS and LR solution in terms of safety or efficacy; however, for excessively large volume liposuction procedures, the differences in formulation might have clinical relevance.

First, there are no published studies of the pharmacokinetics of parenteral (subcutaneous infiltration or intravenous infusion) administration of more than 6 L of NS or LR in the setting of tumescent liposuction. The opinions of "experts" on the subject of fluid and electrolyte homeostasis in liposuction are substantiated by little more than anecdotal experience or dubious clinical dogma.

The effect of tumescent infiltration of 5 L of solution in one patient was closely studied on two different occasions. On the first occasion there was no liposuction after the infiltration. Two weeks later, the second infiltration was followed by liposuction of 1.5 L of supranatant fat.[8] The published results showed that, with or without liposuction, the urine specific gravity decreased and the urine output was greater than 70 mL per hour, both of which indicate that there is no IV fluid deficit. Therefore, IV fluids were not necessary for tumescent liposuction of 1.5 L of supranatant fat. In my personal experience, liposuction of up to 4 L of supranatant fat in moderately obese females does not require IV fluids. This assumes that the patients are fully alert and can take oral fluids whenever they are thirsty.

NORMAL SALINE

The most common lidocaine solvent for the tumescent technique is isotonic physiologic saline (0.9% NaCl), also known as normal saline (NS). NS, as defined by the United States Pharmacopeia, contains 154 mEq/L of both sodium and chloride. Plasma contains 142 mEq Na/L. Typically, sodium bicarbonate ($NaHCO_3$) 10 mEq/L is added to the lidocaine solution in order to neutralize the pH and therefore reduce the stinging pain that otherwise occurs when acidic commercial lidocaine is infiltrated subcutaneously in an alert and fully conscious patient. Therefore, a liter of tumescent solvent will contain 164 mEq of sodium.

LACTATED RINGER'S SOLUTION

A tumescent anesthetic solution without sodium bicarbonate (10 mEq $NaHCO_3$/L) is needlessly painful upon infiltration in an awake patient. The addition of a sufficient amount of $NaHCO_3$ in order to neutralize the pH of an acidic solution of local anesthetic, "takes the sting out" of the local anesthetic when it is infiltrated.

When either LR or NS is the solvent for a tumescent solution of lidocaine and epinephrine, the discomfort upon tumescent infiltration is much less after the addition of 10 mEq $NaHCO_3$/L to the solution. Therefore the addition of bicarbonate is necessary for painless infiltration.

LR solution (USP) contains 130 mEq/L of sodium, 109 mEq/L of chlorine, 29 mEq/L of lactate, 4 mEq/L of potassium, and 2.7 mEq/L of calcium. The average adult produces 1,200 to 1,500 mmol of lactate per day, or approximately 50 to 60 mmol/hour.[15] The liver metabolizes about 60% of this and the kidney metabolizes or excretes the remaining 40%. The liver and kidney can accommodate large lactate infusions without immediate detriment. Large dosages of LR solution, containing 29 mEq/L of lactate, will produce a delayed iatrogenic metabolic alkalosis.

LR has been associated with perioperative complications. Hemodilution associated with LR solution during surgery may predispose to deep vein thrombosis.[6]

The administration of sodium lactate ($NaHCO_3$) in LR solution can cause alkalosis as well as exacerbate preexisting alkalosis. Lactate is metabolized in the liver faster than the kidneys can excrete sodium. The resulting anion deficiency is compensated by an increased production of HCO_3^-, and an alkalosis occurs. Alkalosis may cause cardiac ar-

rhythmias.[13] Alkalosis reduces the effects of vagal stimulation and reduces the level of bradycardia that might result from any given stimulus. Metabolic alkalosis causes an increased oxygen requirement, and will exacerbate cardiac arrhythmias owing to hypoxia or hypokalemia. In alkalotic patients NS should be used for the same indications that LR would be used.

THE DOGMA OF LACTATED RINGER'S SOLUTION

Some surgeons prefer to use LR solution as the solvent for their tumescent lidocaine solutions, purportedly because of LRs "sodium sparing effect", or because LR is "more physiologic" than NS.

Many if not most surgeons have little understanding of the reasons for including lactate in LR (Hartmann's) solution. Furthermore, standard surgical textbooks provide little information to substantiate the traditional preference that surgeons have for the use of LR solution.[10]

The lactate in LR solution is principally intended to produce a gradual reduction of metabolic acidosis. In healthy patients, if there is no acidosis present, then the excess bicarbonate will produce a transient mild metabolic alkalosis, which is promptly corrected by renal bicarbonate excretion. Patients who are critically ill because of illness or trauma, however, may be obligate excreters of acid urine and be unable to excrete the bicarbonate load associated with LR solution, which in turn may cause metabolic alkalosis and produce renal potassium loss.[1]

Because the body contains a huge supply of intracellular potassium as well as the potassium in the extracellular fluid, physiologic saline is quite sufficient for the clinical replacement of intravascular fluids with crystalloid solutions. Transfusion with blood products becomes necessary long before there might be any risk of a potassium deficit as the result of using 0.9% NaCl instead of LR solution.

CHLORIDE LOAD

The rapid expansion of the extracellular fluid (ECF) volume with fluids that do not contain HCO_3^- will produce to a temporary mild dilutional reduction of $[HCO_3^-]$ in the ECF as a result of excessive Cl^- anions in the ECF.[14] For example, a rapid infusion of NS will produce a relatively mild hypercholeremia that produces a compensatory shift of extracellular HCO_3^- into intracellular space. This type of normal-anion-gap acidosis is mild and rapidly corrected by both respiratory compensation and by the kidneys, which excrete NH_4^+ and Cl^-. The kidneys, filter 4000 mmol of HCO_3^- per day, most of which is resorbed, 80% in the proximal tubules and 20% in the distal tubules. Because NS is not buffered and does not contain a net excess of H^+ ions, this mild transient hypercholoremic acidosis does not produce a total body systemic acidosis.

SODIUM LOAD

Sodium ions are, to a considerable degree, excluded from the intracellular space by the Na^+-K^- transmembrane pump. An excessive amount of total body sodium produces an osmotic pressure gradient that pulls water across cell membranes and increases the extracellular fluid volume. Additionally, ingested free water is retained in the ECF by the extra sodium. In progressive degrees, extracellular fluid overload is manifested by peripheral dependent interstitial edema, then intravascular fluid overload with incipient congestive heart failure, and in the extreme, pulmonary edema. Based on this observation, some surgeons have proposed the use of LR solution with its lower sodium content (130 mEq/L of Na) instead of NS (154 mEq/L of Na) as the solvent for tumescent lidocaine solutions. The use of LR is of no benefit except for tumescent infiltration of greater than 10 to 12 L of anesthetic solution.

From our memory of basic chemistry, we know that the molecular weight of of sodium chloride (NaCl) is 58.5 g/mol, and that of sodium (Na) is 22.9 g/mol. By definition, one mole of a substance contains an Avogadro's number of units. The weight of one mole of NaCl is its molecular weight.

The molarity of a solute is defined as the number of moles of a solute per liter of solvent. A liter of water is approximately one kilogram depending on the temperature of the water. Normal saline consists of a 0.9% solution of NaCl = 0.9 g NaCl per 100 mL = 9 g of NaCl per liter. The molarity of NS is therefore (9 g of NaCl/L of H_2O) (mole of NaCl/58.5 g of NaCl) = 0.154 mol of NaCl/

L = 154 mmol of NaCl/L = 154 mEq Na^+/L. Therefore, one liter of tumescent solvent (normal saline plus 10 mEq of sodium per liter in the form of sodium bicarbonate ($NaHCO_3$) contains approximately 164 mEq of Na^+ per liter.

A liter of NS with sodium bicarbonate and a liter of LR differ in sodium content by 34 mEq/L (164 mEq/L − 130 mEq/L). This difference is clinically insignificant for routine tumescent infiltration of an average of less than 5 to 7 L of tumescent subcutaneous fluid. The interval of time required for systemic absorption of this volume of tumescent fluid is approximately 24 to 36 hours, however, 5 L of tumescent solvent (NS with 10 mEq $NaHCO_3$) exceeds the amount of sodium in 5 L of LR by 170 mEq of sodium ion = 170 mmol of NaCl = 0.17 mol NaCl = (0.17 mol) (58.5 g NaCl/mol) = 9.95 g of NaCl. To put this in perspective, a 1-lb (450 mg) bag of pretzels contains approximately 9 g of sodium chloride. Therefore, LR does have some sodium sparing effect, but this is only significant in the range of excessively aggressive tumescent liposuction that infiltrates more than 10 to 12 L of tumescent solution.

The difference between NS and LR should be of little concern for a surgeon who is primarily concerned with patient safety. Problems with fluid overload are easily avoided by not attempting huge-volume liposuction in a single surgical procedure. A large volume of aspirated fat removed by serial liposuctions is far safer than a single surgery attempting to do it all at once.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	William W. Cimino	Examiner:	Laura A. Bouchelle
Serial No.:	10/600,118	Group Art Unit:	3763
Filed:	June 20, 2003	Docket. No.:	40206.19US01
Title:	"Precision Fluid Delivery System and Method for Surgical Procedures"		

SECOND SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. § 1.132 BY DR. MARK L. JEWELL, M.D.

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Mark L. Jewell, declare:

1. A declaration of mine (the previous declaration) was submitted to the United States Patent and Trademark Office (USPTO) on February 22, 2011 in U.S. Patent Application Serial No. 10/600,118 (the present application) identified above. The previous declaration was submitted to provide objective evidence of nonobviousness for the invention claimed in the present application.

2. I am aware that the present application is currently rejected by the USPTO, and that the Examiner indicated in the latest office action that the previous declaration did not include enough information to establish that previously available devices did not satisfy the long felt need of delivering fluid rapidly and accurately to fill breast implants and sizers.

3. I reaffirm the statements that I made in the previous declaration. This Second Supplemental Declaration is being submitted to supplement the previous declaration, and in particular to provide facts regarding the deficiencies of prior devices used to deliver fluids for filling breast implants or sizers.

4. As indicated in paragraphs 8 and 9 of the previous declaration, it is my understanding that the invention claimed in the present application is embodied in a precision fluid management system (PFMS) sold as part of Sound Surgical's VASER system, which I have used since its initial release.

5. I reiterate my statement from paragraph 12 of the previous declaration, namely that prior to the release of the VASER system incorporating the PFMS, I was not aware of any device that could deliver fluid with the necessary speed and accuracy for filling breast implants or sizers.

6. In paragraphs 13-15 of the previous declaration, I summarized the two common systems and methods that were available for delivery of fluid to fill breast implants or sizers, namely the use of prefilled syringes and the use of a pressure collar with intravenous (IV) bags. I also described some deficiencies of the two common systems, which made them inadequate for delivering fluid rapidly and accurately.

7. Exhibit A of this Second Supplemental Declaration is an article, Gerald Bernstein, "Instrumentation for Liposuction," *Dermatologic Clinics*, vol. 17 (October 1999) p. 735, which describes the two systems that I mentioned in the previous declaration. Exhibit A describes some of the deficiencies in each of these methods and systems. Although Exhibit A focuses on use of these methods and systems in lipoplasty procedures, the deficiencies are equally applicable to filling of breast implants and sizers. Exhibit A does not disclose all of the deficiencies in the prior systems and methods, but the deficiencies pointed out in Exhibit A support my statements from the previous declaration indicating that the systems and methods previously available were deficient and did not adequately meet the need of rapidly and accurately delivering fluid for filling breast implants or sizers.

8. On page 736, Exhibit A describes the use of syringes for delivering fluid. As I stated in paragraph 14 of the previous declaration, syringes delivered fluid too slowly, which prolonged procedures. In paragraph 19 of the previous declaration, I also stated that prolonging a procedure could lead to surgeon fatigue. Exhibit A states with respect to syringes that "[t]hese devices are very effective although they also have the drawback of being slow. Also, frequent use of the refillable syringe over large areas may result in repetitive motion injury to the surgeon or nurse . . . ." *Exhibit A, page 736.* Exhibit A therefore supports my statements that use of refillable syringes did not provide adequate methods or systems for rapidly and accurately delivering fluids to fill breast implants or sizers because of how slow the fluid was delivered and the possibility of surgeon fatigue or injury from repetitive motion.

9. I noted in paragraphs 14-17 of the previous declaration that systems that utilize pressure collars did not provide the necessary accuracy. Exhibit A further describes the use of pressure collars and IV bags for delivering fluid to fill breast implants or sizers. Exhibit A refers to the systems that use pressure collars and IV bags as "power IV infusors," *See Exhibit A, page 737.* Figure 2 in Exhibit A shows an example of one of the power IV infuser systems, which is similar to the device shown and described in Exhibit D of the previous declaration. As can be seen from Figure 2 in Exhibit A, the power IV infuser systems use line markings on the IV bag to measure the volume of fluid infiltrated into a patient, which is subject to inaccurate readings by a nurse or surgeon.

10. Exhibit A further describes other deficiencies of the power IV infusors including, "if the pressure is excessive, the tubing [connecting the IV bag to the infusion needle] may separate from the infusion needle and result in a spill. For this reason, IV infusion kits with luer-loks are less likely to become disconnected during use." *See Exhibit A, page 737.* Exhibit A recommends use of a handle with an on-off control in order to make the power infuser "less messy and more efficient." Spilling infusion fluid can create serious situations beyond being messy. Spilled fluid makes it difficult for a nurse or surgeon to determine the volume of fluid that has been used to fill a breast implant or sizer. Exhibit A reinforces my statements that use of

pressure collars and IV bags did not provide an adequate system and method to accurately deliver fluids to fill breast implants or sizers.

11. Exhibit A further describes systems that use peristaltic pumps for delivering fluids to fill breast implants or sizers. Figure 3 of Exhibit A illustrates some examples of systems that use peristaltic pumps. The systems do not provide features beyond line markings on an IV bag for determining the amount of fluid delivered. Line markings do not provide the necessary accuracy for determining the volume of fluid used to fill breast implants or sizers.

12. As I noted in paragraph 11 of the previous declaration, accurately monitoring the amount of fluid used to fill breast implants or sizers is important. If sizers are used, a surgeon must have an accurate reading of the amount of fluid used to fill the sizer in order to properly select the permanent implant. In situations in which fluid is used to fill the permanent implants, the amount of fluid used to fill a first implant must be accurately known in order to fill the second implant with the same amount of fluid and ensure that the patient has the desired symmetrical appearance. The power IV infusers and peristaltic pump systems, in use before the availability of Sound Surgical's PFMS, relied on line markings on an IV bag, which are subject to inaccurate readings that can have significant consequences such as inserting wrong sized implants in a patient, or creating an asymmetric look in a patient.

13. I refer again to my statements in paragraphs 21 and 22 of the previous declaration. The PFMS provided a device that for the first time enabled aesthetic surgeons to deliver fluids both quickly and accurately for filling breast implants or sizers. The prior art devices and methods, described in Exhibit A of this Second Supplemental Declaration did not satisfy the need for rapidly and accurately delivering fluids to fill breast implants or sizers. Exhibit A supports my previous statements indicating the deficiencies in these devices.

14. I have also briefly reviewed the references that the USPTO has used to reject the claims in the present application during the course of examining the present application. None of the methods or devices described in the cited references satisfies the need that existed before the PFMS for rapidly and accurately delivering fluid to fill breast implants or sizers.

15. Some of the references previously used to reject the claims of the present application describe the use of intravenous (IV) systems that do not deliver fluids rapidly enough or with sufficient pressure to fill breast implants or sizers (e.g., U.S. Patent No. 4,670,007 to Wheeldon et al.; U.S. Patent No. 5,910,135 to Hadzic et al.; and U.S. Patent No. 4,650,464 to Ruiz et al.). These methods and devices are simply not suitable for filling breast implants or sizers.

16. Other references used to reject the claims of the present application (e.g., U.S. Patent No. 4,650,462 to DeSatnick et al.; U.S. Patent No. 6,319,221 to Savage et al.; and U.S. Patent No. to 5,178,606 to Ognier et al.) describe the use of continuous flow systems that do not deliver a desired volume of fluid. Rather, these systems continuously provide fluid to an anatomical location. These methods and systems cannot be limited to delivering a desired volume of fluid, because the amount of fluid delivered will change depending on the needs of a procedure. Additional fluid may need to be delivered to keep a cavity extended, e.g., a knee or uterine cavity, or less fluid may be delivered if the pressure within the anatomical location becomes too high. These methods and devices therefore did not satisfy the need for rapidly and accurately delivering a desired volume of fluid to fill breast implants or sizers.

17. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements ar oh e made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the instant application or any patent issued thereupon.

Date: 12-22-2011

Mark L. Jewell

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of: William W. Cimino	Group Art Unit: 3763
Application No.: 10/600,118	Examiner: Laura A. Bouchelle
Filed: June 20, 2003	Confirmation No.: 9143
Atty. File No.: 6613-19 (previously 40206.0019US01)	

For: PRECISION FLUID DELIVERY SYSTEM AND METHOD FOR SURGICAL PROCEDURES

SECOND SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. § 1.132 BY DR. MARK L. JEWELL, M.D.

EXHIBIT A

Article: Gerald Bernstein, "Instrumentation for Liposuction," Dermatologic Clinics, vol. 17 (October 1999)

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INSTRUMENTATION FOR LIPOSUCTION

Gerald Bernstein, MD

Since the introduction of liposuction into the United States in 1982, instrumentation for this procedure has undergone many significant changes. Great innovation and creativity have brought new and increasingly efficient instruments to the liposuction surgeon. Many of the improvements in both the safety and effectiveness of liposuction have been a result of the introduction of new instrumentation. Indeed one of the key factors in the development of liposuction as a viable procedure was the change in instrumentation from the sharp to the blunt cannula. Further developments, most notably the advent of the tumescent technique, developed by Dr. Jeffrey Klein in 1985, radically modified liposuction and further spurred the development of new innovative instrumentation to meet the demand.[13]

In addition to instrumentation directly used for liposuction, other instruments and equipment of a more ancillary or supportive nature are needed as well. This includes those necessary to increase patient safety, monitoring equipment, equipment to clean and sterilize the instruments, and products for postoperative care.

INSTRUMENTATION AND EQUIPMENT FOR INFUSING THE TUMESCENT SOLUTION

The tumescent solution, as originally developed by Dr. Jeffrey A. Klein, consisted of a solution of saline containing lidocaine (0.05% to 0.1%), adrenalin (1:1,000,000), and 12.5 mE of sodium bicarbonate to reduce stinging.[13, 14] This solution has been modified by some who add triamcinolone, 10 mg/L. In addition, many liposuction surgeons have replaced saline with Ringer's lactate, which changes the pH and obviates the need for sodium bicarbonate. It has been repeatedly shown that the infusion of this solution into the subcutaneous fatty layer will induce local anesthesia and vasoconstriction, which allow the procedure to be undertaken without additional general anesthesia and with greatly enhanced safety.[8, 13, 14, 18] Intraoperative and postoperative bleeding, which originally imposed serious limitations on the amount of fat that could be extracted, have been largely controlled by use of this solution. Limits to the amounts of lidocaine that can be safely infused have been discussed elsewhere. Although there is considerable discussion about the actual safe limits of lidocaine, 55 mg/kg, appears to be generally accepted as safe for most healthy patients.[20] Dr. Klein has suggested potential problems resulting from drug interactions with lidocaine and other substances, primarily selective seratonin reuptake inhibitors (SSRI) such as sertraline (Zoloft), which are metabolized by the liver, microsomal p450 3A4 (CYP3A4) enzyme system.[15] However, the actual potential for serious interactions with individuals who have

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normal liver function is yet to be demonstrated. The total volume of infused saline may also be a factor affecting the patient's safety and would depend on the patient's kidney, cardiac function, and blood pressure.

WARMING OF THE TUMESCENT SOLUTION

Many physicians will warm the tumescent solution prior to instillation into the subcutaneous space. Warmed saline probably produces less discomfort to the patient than the cool solution. In addition, because of the large volume of saline that is often infused, cool saline has the potential to lower the core temperature. This has been shown to increase the risk of morbid cardiac events and increase the potential for infection. Compromise of the clotting function and prolonged healing have been described as well.[6, 12, 22] Many physicians manage these problems by the use of warmed solutions. The solutions can be warmed either in a water bath made for this purpose or in microwave ovens. If the solution is to be warmed in a microwave oven, the physician must identify the exact duration that the IV bags can be safely placed in the microwave. As microwave ovens have different energy levels, an exposure that will safely warm an IV bag in one microwave oven may bring the temperature to an unacceptably high level in another. Whichever mechanism is used to warm the IV bags, it is critical that the temperature be carefully monitored to ensure that excessively hot tumescent solution is not being infused into the patient.

INSTRUMENTATION AND EQUIPMENT FOR INFUSION OF THE TUMESCENT SOLUTION

There are a variety of techniques and devices for effectively infusing the tumescent solution into the subcutaneous space.[9] Many of these devices are available commercially. The most simple technique is to use a 60-mL syringe attached to an infusion needle. The syringe is emptied individually and refilled by the nurse. Although simple and effective, this is a very inefficient technique. It can prolong the procedure and may lead to incomplete infiltration, especially when applied to a large surface area. It is, however, effective for liposuction touch-ups or treatment of very small areas. In addition, it can be used to harvest small amounts of fat for lipoinjection or for treatment of small lipomas.

A refinement of the simple syringe technique is the use of a syringe with a two-way stopcock. This will allow rapid refilling of the syringe from an IV bag. Several effective devices have been developed including many with spring-driven syringes to allow rapid refilling of the syringe after it has been emptied (Fig. 1). Many other reusable and resterilizible syringe-stopcock combinations have been developed that will more rapidly infuse solution. These devices are very effective although they also have the drawback of being slow. Also, frequent use of a refillable syringe over large areas may result in repetitive motion injury to the surgeon or nurse; however, these devices can be very useful for treatment of small areas such as the neck or knees,

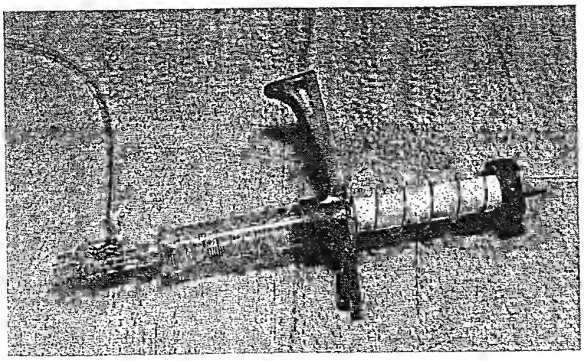

Figure 1. Spring-driven syringe with two-way stopcock (McGhan Medical Corp., Santa Barbara, CA). Plastic hose connects to IV bag containing tumescent solution. Allows rapid infusion of tumescent solution.

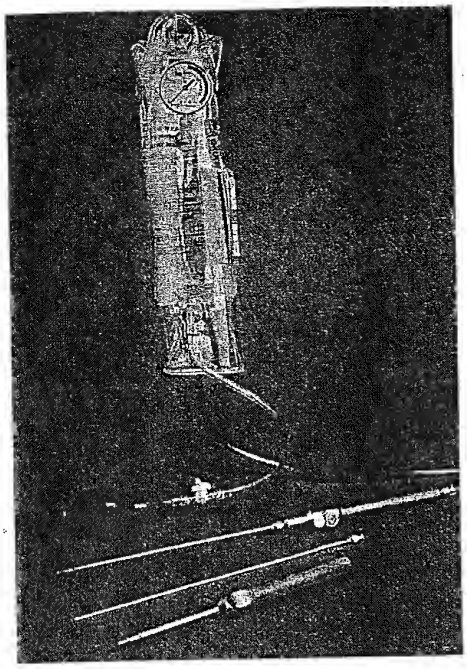

Figure 2. Intravenous (IV) power infusion device fits over the IV bag. Gauge indicates degree of pressure and mechanical switch on handle controls flow of tumescent solution.

touch-ups, or areas anesthetized to harvest fat for lipoinjection.

Power IV infusors (Byron Medical, Tucson, AZ) can be used to rapidly inject tumescent solution for liposuction patients (Fig. 2). This is an inexpensive way to rapidly infuse large volumes of tumescent solution. These devices usually cost less than $50.00. They fit over an IV bag and are inflated with a bulb pump similar to a sphygmomanometer. Indicators are usually provided to demonstrate an optimal and safe amount of pressure to infuse the solution. The IV bag is connected to the infusion needle with ordinary IV tubing; however, if the pressure is excessive, the tubing may separate from the infusion needle and result in a spill. For this reason, IV infusion kits with luer-loks are less likely to become disconnected during use. In addition, to more effectively use this approach, a handle with an on/off control should be present at the fingertips of the operator to easily turn the flow of solution on or off (see Fig. 2). Several such devices exist, such as the Hunstad Handle. This is a small handle that connects to the tubing on one side and the infusion needle on the other side. There is a simple thumb valve that is depressed to initiate the flow. This device will make the power infusor much less messy and more efficient.

The most efficient and effective way to infiltrate the tumescent solution is with a peristaltic pump (Fig. 3). Several varieties of variable-speed peristaltic pumps are available. Some use modified IV tubing whereas others use resterilizable silicon tubing. The tubing is connected directly to the IV bag, threaded through the power pump, and then connected directly to the infusing needle either with or without an intervening handle. Most pumps have variable speeds ranging from zero to over 400 to 600 mL/min. The most efficient pumps have two foot pedals so that one can be placed on each side of the operating table. In this manner, the operator can easily move from one side of the table to the other to access different parts of the body and make the infusion process more rapid. Otherwise, it is necessary to use either a hand switch, which is awkward and may compromise sterile technique, or a foot pedal, which has to be moved to each side of the table as the operator moves.

The limiting factor on the rate of flow of the tumescent solution is the size of the tubing and, most importantly, the size of the needle. A peristaltic infusion pump rated at 400 mL/min will only be able to deliver approximately 75 mL/min through an 18-gauge needle. A 15-gauge multiport needle, "garden-spray type", will accommodate up to 200 mL or more per minute. Also, the greater the diameter of the infusion tubing, the more rapidly the tumescent solution can be infused. Several infusion pumps have dual heads, allowing two operators to infuse the same patient simultaneously. This, however, must be done without the one operator interfering with the activities of the other. Some pumps actually have dual variable-speed pumps in the same device allowing for customization of the infusion process.

INFUSION NEEDLES

Tumescent solution can be instilled with a variety of needles. Klein recommends starting the infusion very slowly with a 25-gauge spinal needle (Jeffrey A. Klein, MD, personal communication, 1996). After a low level of anesthesia has been achieved, the size of the infusion needle is increased ultimately to 18 gauge. Other physicians will start with larger

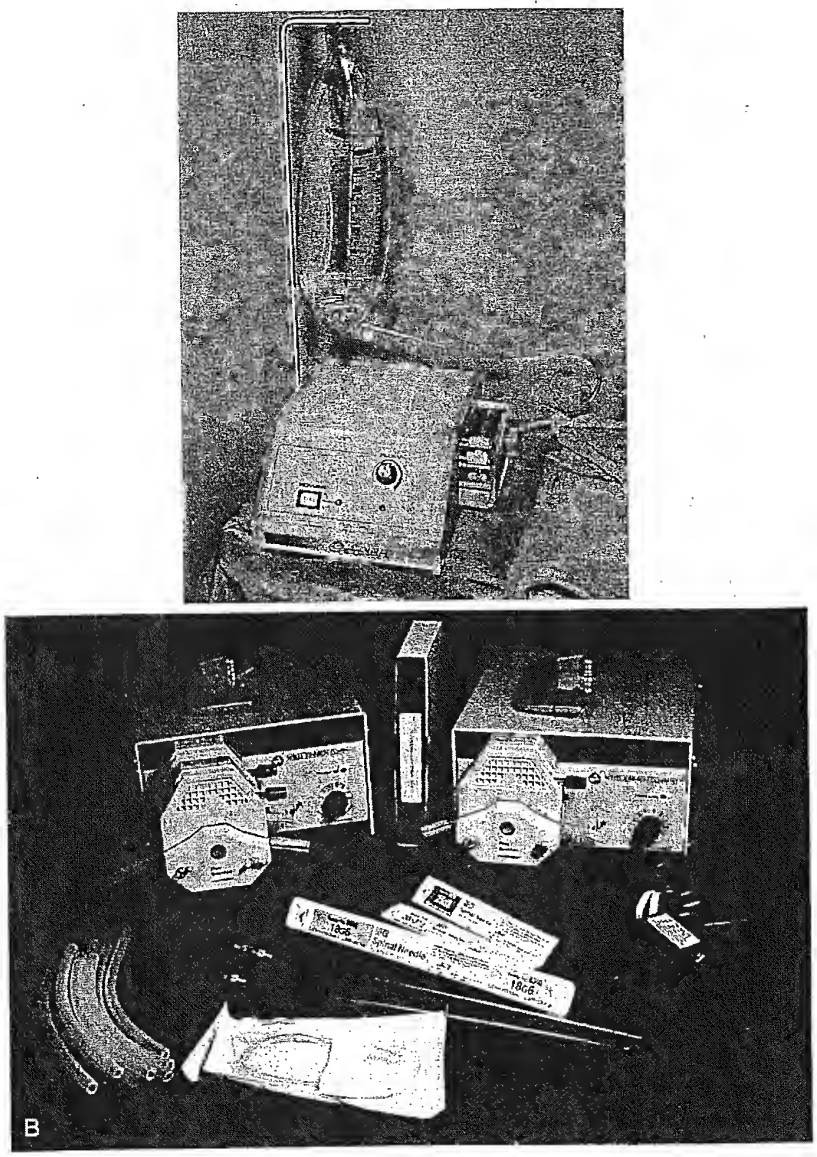

Figure 3. *A* and *B*, Various mechaical pumps for infusing tumescent solution. Most modern pumps have variable speeds (*A*, Tiemann/Bernsco Co., Hauppage, NY; *B*, Wells Johnson Co., Tucson, AZ).

needles, such as 18- or even 15-gauge multiport needles. The latter usually have 4 to 10 ports, which are situated on the last two inches of the cannula. The latter allow a much more rapid rate of infusion. Blunt tips tend to reduce the amount of discomfort and many patients will receive tumescent solution through a blunt-tipped multiport 15-gauge needle with little or no discomfort.

When patients experience pain, reducing the rate of infusion will often bring about immediate relief of the discomfort. After a small amount of solution has been instilled and anesthesia has been initiated, the infusion rate can be increased without further discomfort. Many operators will start by instilling deeply and then at a progressively higher level until the superficial plane has been anesthetized, therefore achieving firm tumescence.

LIPOSUCTION ASPIRATION EQUIPMENT

Liposuction is generally performed by two methods: the syringe method and the power pump method. The syringe method is enthusiastically supported by many liposuction surgeons.[7, 23] With the syringe method, the vacuum for liposuction is generated by withdrawing the plunger of a syringe while the cannula is in the place. Several locks exist that will hold the syringe out and maintain the negative pressure during the procedure (Fig. 4). When the syringe (usually a 60-mL syringe) is filled, it is withdrawn from the patient and handed to an assistant, who will empty the syringe while the physician continues the procedure with a second syringe. By trading off between the physician and the assistant, the procedure can move along quite rapidly. Most physicians who use the syringe method insist that their rate of aspiration is as rapid as aspiration conducted with a machine pump. A variety of cannulas have been made that fit over Toomey-type syringes. Cannulas also exist that will fit catheter syringes. The latter are somewhat less expensive than the Toomey. Also many cannulas have luer-loks and will fit on any standard syringe, which can then be used to aspirate the fat. In the latter instance, however, it is noted that the opening is relatively small. This will slow down the transfer process, as the fat often has to go from a larger-diameter cannula through the smaller diameter of the opening of the syringe.

Although there is diversity of opinion as to which is the preferable technique, syringe or machine-generated vacuum, most surgeons performing lipoinjection will harvest fat directly into a sterile syringe rather than with a pump. Although both syringe and mechanical aspiration methods achieve the same vacuum (i.e., 29 inches of Hg at sea level) the syringe is felt to be less traumatic to the fat cells. It is much easier, however, to maintain the fat in a sterile environment using the syringe technique. Also, a recent article has demonstrated viability of human lipocytes after the syringe method harvest.[12]

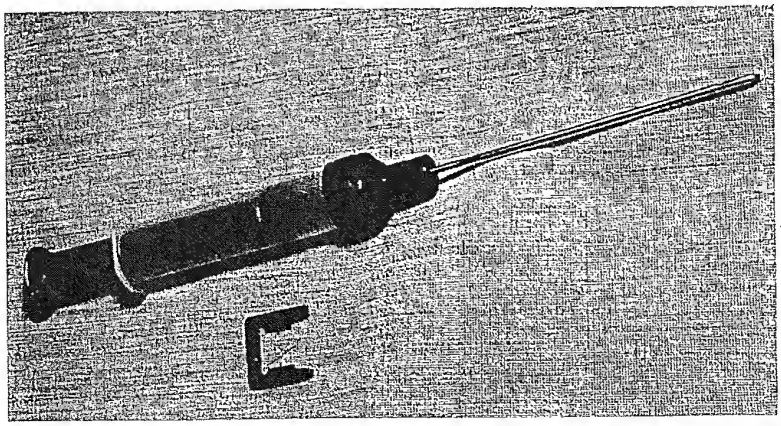

Figure 4. Liposuction cannula attached to a 60 mL *Toomey* type syringe. Vacuum is generated by withdrawing the plunger while the cannula is in the subcutaneous fatty space. A lock, which fits over the flange of the syringe, holds the plunger in place maintaining the negative pressure.

MECHANICAL ASPIRATION PUMPS

There are a variety of pumps made by several manufacturers of liposuction equipment (Fig. 5). Most pumps are either vane or piston-driven. The latter are more powerful but tend to be noisier. This may be a significant consideration when one is performing liposuction for several hours, as a high noise level can create tension and increase the level of stress during the procedure. Most machines will generate one atmosphere of negative pressure - 29 inches of Hg, relatively rapidly. Of course, at higher altitudes the level of negative pressure is reduced. In Colorado, for example, 23 to 24 inches of negative pressure is the maximum level of negative pressure that can be achieved. A recent article has suggested that more fat can be efficiently removed at 20 inches of Hg.[5] Also, many liposuction surgeons like to reduce the pressure while doing liposuction of the face, neck, and submental area. Some of the higher-quality machines have the capability of varying the pressure.

PREOPERATIVE AND INTRAOPERATIVE ULTRASONIC LIPOSUCTION

Ultrasound has been used in liposuction both internally and externally. Internal, ultrasonic-assisted liposuction uses cannulas that oscillate at approximately 15,000 to 30,000 Hz. The lipocytes are imploded, which liquefies the fat. This modality is adequately discussed elsewhere (see the article by Lawrence and Coleman in this issue) and will not be reviewed in this article.[2, 16, 24, 25]

The application of external ultrasound has been advocated as well. This technique uses ultrasound in the 1 MHz frequency at 2 to 3 W/CM^2 applied to the skin overlying the areas to be treated, after instilling the tumescent solution but before performing the actual li-

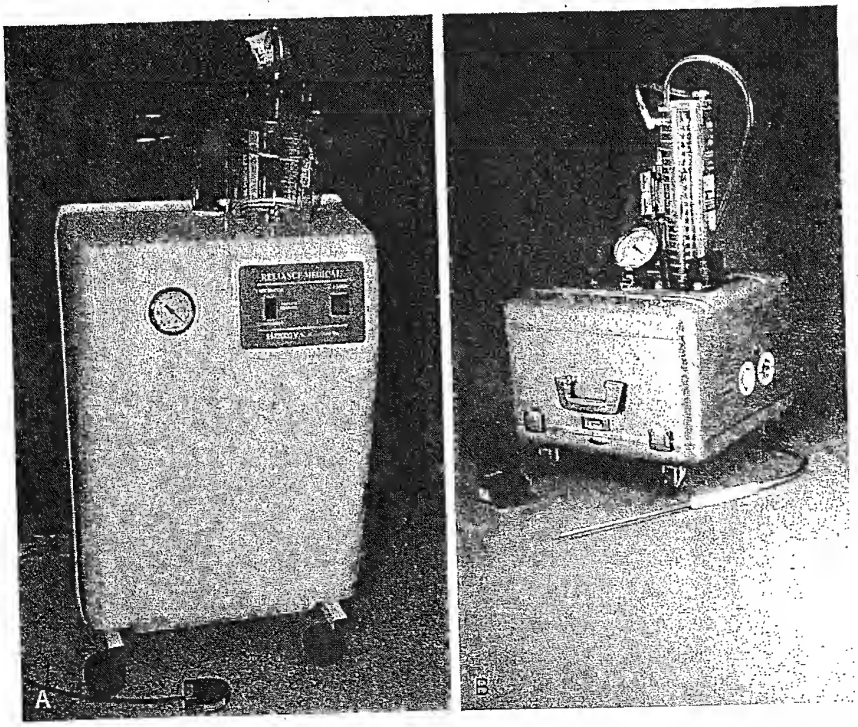

Figure 5. Examples of electric-powered liposuction aspirators. *A*, This respirator features a rigid plastic collection canister (Tiemann/Bernsco Co., Hauppage, NY), which is discarded after each use. There is an internal valve that prevents overflow of fat and fluid into the machine. It is relatively inexpensive. The collection canister featured in *B* has a soft plastic bag placed in an external rigid canister (Byron Medical, Tucson, AZ).

posuction surgery. In this instance, the actual aspiration is performed in the conventional fashion with hollow cannulas and an aspirating machine. This subject is also discussed in the article by Lawrence and Coleman and will not be further reviewed in this article.[3, 10]

COLLECTION DEVICES AND FILTERS

Modern collection devices are either made of glass or plastic materials. The graduated glass collection devices are becoming relatively scarce and are often hard to replace when broken. Their fragility somewhat limits their usefulness and, in fact, they are probably much less efficient because they have to be emptied and cleaned after each use. This is less of a problem in small-volume cases, where one glass jar will be adequate for an entire case, than in large volume cases, where the collection jars have to be frequently emptied throughout the course of a procedure.

Plastic collection devices are either rigid or soft. The rigid canisters can be 1-, 2-, or even 3-L graduated containers that are made of clear plastic (see Fig. 5*A*). This allows easy estimation of the aspirated volumes of fat and fluid. They generally have multiple ports, allowing various sizes of tubing to be connected. Some of the better-quality products have an internal shut-off device, which prevents overflow. If overflowing liquids are aspirated into the machinery of the pump, the aspirator will be ruined and require servicing. Most manufacturers will not warranty aspirator pumps that have been damaged by fluid. The rigid plastic containers will occasionally crack, allowing in air, lowering vacuum pressure and requiring replacement.

There is some variation in the soft collection devices or bags. To be effective they are set in a rigid, clear-plastic, graduated outer container (see Fig. 5B). In order to keep the collection bags expanded (and therefore able to receive the aspirated fat), some of the vacuum must be diverted into the space between the bag and the outer canister. The weakness of this collection system is that if air leaks develop in the rigid column, the internal liner will collapse and the liposuction procedure must stop. Unfortunately cracks do occur, especially around the metal or plastic connectors. If a standby rigid outer column is not available, one would have to find some way to seal the leak or else the operation will have to be halted.

There are two types of aspiration hoses: the stiff clear-plastic hoses and the soft, somewhat thinner hoses. The rigidity of the clear-plastic hoses make them clumsy and adds weight to the procedure. Many physicians prefer the thinner, softer hoses, which are equally efficient and effective in moving the fat from the cannula into the collection system. Because they are soft they cause less drag on the operator's hand. The weight and stiffness of the thicker clear-plastic hoses will often require a surgeon to have a standby nurse doing nothing more than supporting the hose during the procedure. The hoses used in liposuction cannot be resterilized. They become stiff, opaque, and fragile in an autoclave. Therefore, they must be discarded after each use.

CANNULAS

Liposuction sparked the development of many new cannulas, which were invented both by liposuction surgeons and innovative manufacturers. Originally many curved forms were available; however, most modern liposuction cannulas are now straight. The cannulas themselves are made of stainless steel, but the handles can be either stainless steel, aluminum, deldrin, or even brass. The latter are quite heavy. When liposuction first appeared in the United States, standard cannulas were up to 10 mm in diameter or even larger. Fifteen millimeter cannulas were used as well. Now, cannulas tend to be small; the more common cannulas used by dermatologic and other surgeons are 2- to 4-mm in diameter. Dr. Klein developed cannulas that were measured in gauge rather than millimeters. The gauge equivalents are indicated in Table 1.

The chief factors involved in selecting a cannula are the tip configuration, the diameter, and the length and shape of the handle. The handles should be of a size that is comfortable for the operator. Because liposuction cannulas must be gripped continuously for

Table 1. GAUGE-MILLIMETER EQUIVALENTS

Gauge		Equivalent
8 gauge	=	4.2 mm
10 gauge	=	3.4 mm
12 gauge	=	2.8 mm
14 gauge	=	2.2 mm

many hours at a time, an ill-fitted handle can result in repetitive motion injury. Therefore, one should carefully select cannulas that comfortably fit the hand.

The length of the cannula itself should be adequate to reach all parts of the treated area. Longer cannulas may be somewhat less controllable than shorter cannulas. The use of very long cannulas, especially in the hands of inexperienced surgeons, can sometimes lead to the cannula being accidentally misdirected during the procedure. This is especially true when encountering areas that are more fibrotic than surrounding areas, as in old surgical scars and in areas that are being treated after prior liposuction. The use of the shortest possible cannula to perform the job is encouraged, especially in the hands of inexperienced surgeons or when using very thin cannulas.

The handles of virtually all liposuction cannulas have a depression or dimple where the thumb should be placed (Fig. 6). This dimple indicates the up position and, when one's thumb is place, the openings can be expected to be exactly 180° away and therefore always pointing in the "downward" [correct] direction. The dominant direction of the ports of most cannulas is downward. However, some cannulas, such as the radial triport, have two openings that are angled 60° from the up position. Therefore, there is potential for trauma to the dermis and dermal blood vessels if these cannulas are used in a very superficial plane. This may be a theoretical consideration as no significant ill effects to the dermis have been specifically attributed to the use of radial triport or similar cannulas. Some surgeons prefer a small hole in the depression of the handle, which allows them to control the vacuum with their thumb.

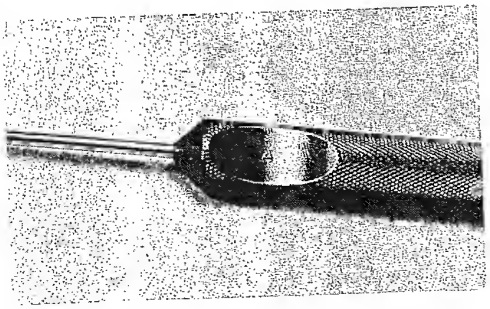

Figure 6. Cannula with typical dimple in the handle for placement of the thumb. This depression indicates the up position for the cannula.

The tips of cannulas generally come in one of three shapes: bullet, spatula, or rounded (Fig. 7). For most liposuction the use of bullet and spatula cannulas is encouraged because of the reduced friction and therefore greater ease of use.

The actual number, pattern, and size of the openings or ports in the cannulas greatly determine their relative aggressiveness. Although many tip configurations have been developed since liposuction was first introduced, there are a dozen or so cannulas that have survived to the present because of their usefulness and effectiveness. I categorize cannula port configurations as being conservative, moderately aggressive, and very aggressive. Note that there is no uniformity in the size or shapes of the ports of cannulas made by different manufacturers. Therefore, similar cannulas made by different manufacturers will differ in the degree of aggressiveness (Fig. 8). Also, cannulas are now available that are coated with polytetrafluoroethylene, which can reduce resistance during liposuction (Fig. 9). This is especially useful when operating in fibrous areas such as love handles and gynecomastia.

Conservative cannulas will have one or two openings. The openings are usually somewhat set back from the actual tip. The ports on the conservative cannulas may be somewhat small. Single- or dual-port standard or spatula cannulas are examples of conservative cannulas (see Fig. 8).

Moderately aggressive cannulas include some larger dual-port cannulas such as the Texas cannula. Cannulas with ports at the very tip tend to collect fibrous tissue during the procedure. They have to be cleared regularly throughout the procedure. Examples include dual-port standard and spatula cannulas with larger openings, two-port Eliminator openings, Texas cannula, the Fournier, and the two-port standard cannula (see Fig. 8).

More aggressive cannulas include the Cobra and Pinto cannulas, which have two openings at the tip and one below. Others, such as the Becker and Eliminator cannulas, are also considered rapid harvesters of fat (see Fig. 7).

Most liposuction surgeons will settle on a relatively small number of cannulas with which they have experience and are comfortable. One is encouraged to have a number of "favorite" cannulas in various diameters and length. Occasionally cannulas become contaminated during surgery. Not having another sterile cannula on hand will require the

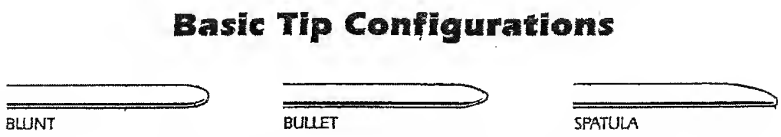

Figure 7. Examples of basic liposuction cannula tip configurations.

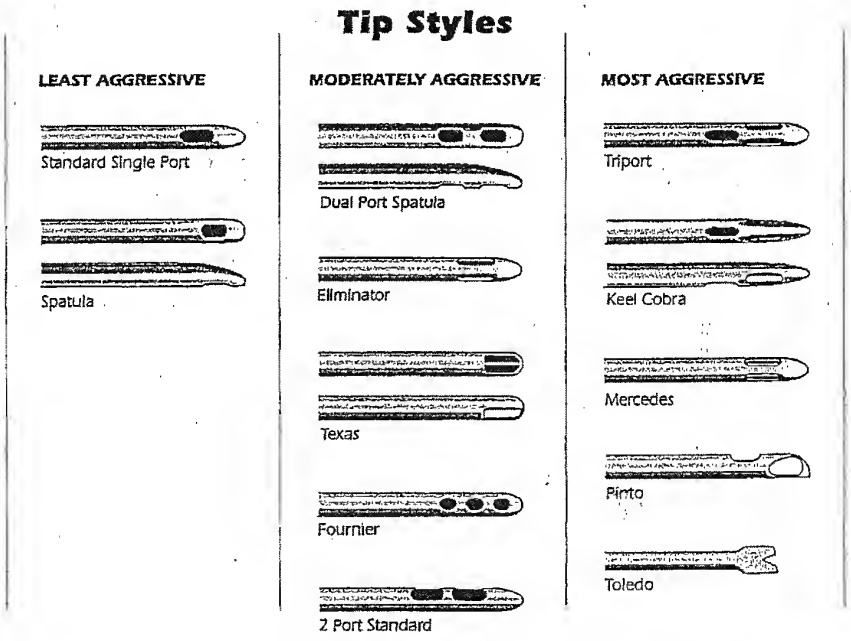

Figure 8. Comparison of identical tri-port cannulas made by different manufacturers. Note the difference in the size of the ports. The larger one is expected to be a more aggressive cannula than the smaller.

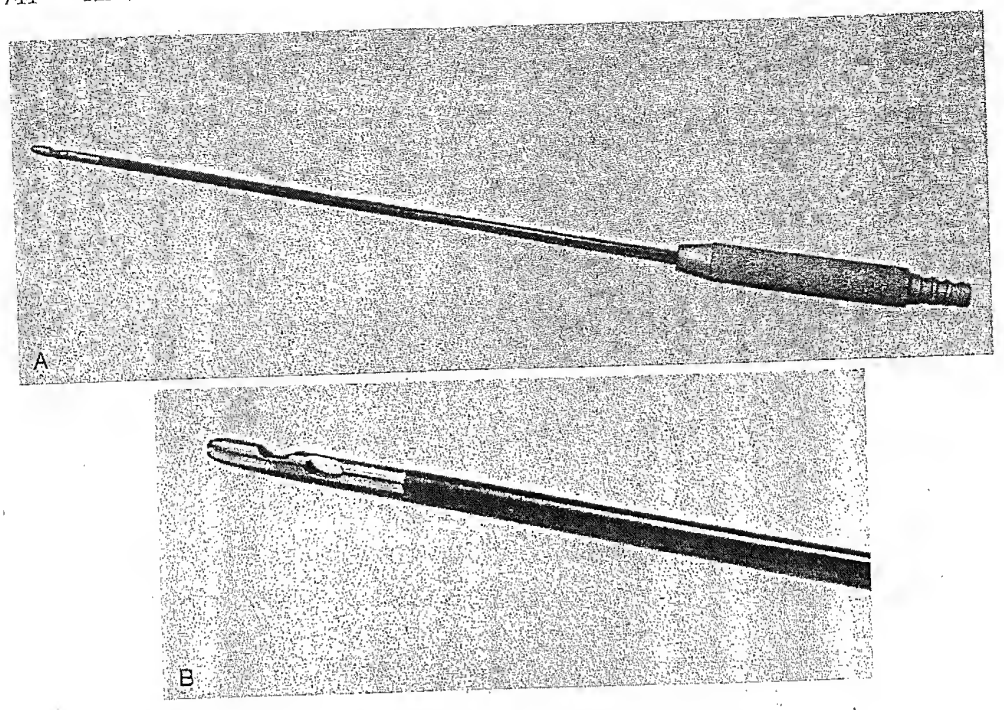

Figure 9. *A*, Example of PTFE cannula of a tri-port (Eliminator) type design. *B*, close-up view.

procedure to cease while the cannula is being cleaned and resterilized.

CLEANING CANNULAS

Of course cannulas used for liposuction must be adequately cleaned and sterilized after each use. Adequate cleaning includes irrigation of the cannula with a syringe or other pressure device and use of a brush to remove particulate matter from the cannula. To effectively remove all debris, however, the use of an ultrasonic cleaner is urged. Cleaners are available in adequate lengths to accommodate most liposuction cannulas. After the cannulas have been removed from the ultrasonic cleaner they are again rinsed, dried, and sterilized in an autoclave. A large autoclave will be necessary to accommodate the length of liposuction cannulas.

THE STERILE OPERATING THEATER

Ideally, the operating room for liposuction should be large enough for the operating table to be placed in the center of the room. The surgeon can then approach the patient from all directions. As most surgeons are not ambidextrous, it is important to be able to approach the patient from the right or left side to adequately access all fatty deposits. A table with an electric motor or pneumatic pump will allow the surgeon to change the level of the table during the procedure. This will be more convenient and comfortable for the surgeon and there will be less strain to the back, shoulders, and arms. Comfortable access to all fatty deposits can be expected to provide a better and even cosmetic result. In addition, there should be adequate ventilation and facilities for heat because patients often become cold during the course of the procedure. There should also be adequate room for the machinery, equipment, and supporting Mayo stands, etc., which are used during the procedure while still allowing ample room for the surgeon and staff to perform their tasks.

Liposuction has been demonstrated to be an extremely safe procedure.[9] Nonetheless, the maintenance of a sterile environment is elementary. Sterile gowns, adequately sterile

draped tables, instrument trays, and other equipment may be necessary to maintain an aseptic operating field. Several sterile "basic" packs are available at low cost and can cover all operating and instrument surfaces with waterproof or water-resistant disposable fabrics (Fig. 10). These are available with sterile gowns for the physician as well. Not only do they transform the operatory into a credible operating room, they also go far to ensuring a safer, sterile environment for the patient and a more favorable outcome.

MONITORING

It is considered appropriate by many surgeons to monitor all but the simplest liposuction procedures. Monitoring usually includes blood pressure, pulse, oxygen saturation, and echocardiogram. Some surgeons measure body temperature as well. Many devices are available to perform these monitoring functions. The monitors can either be separate or combined in a single computerized monitor (Fig. 11). The latter are more efficient and save

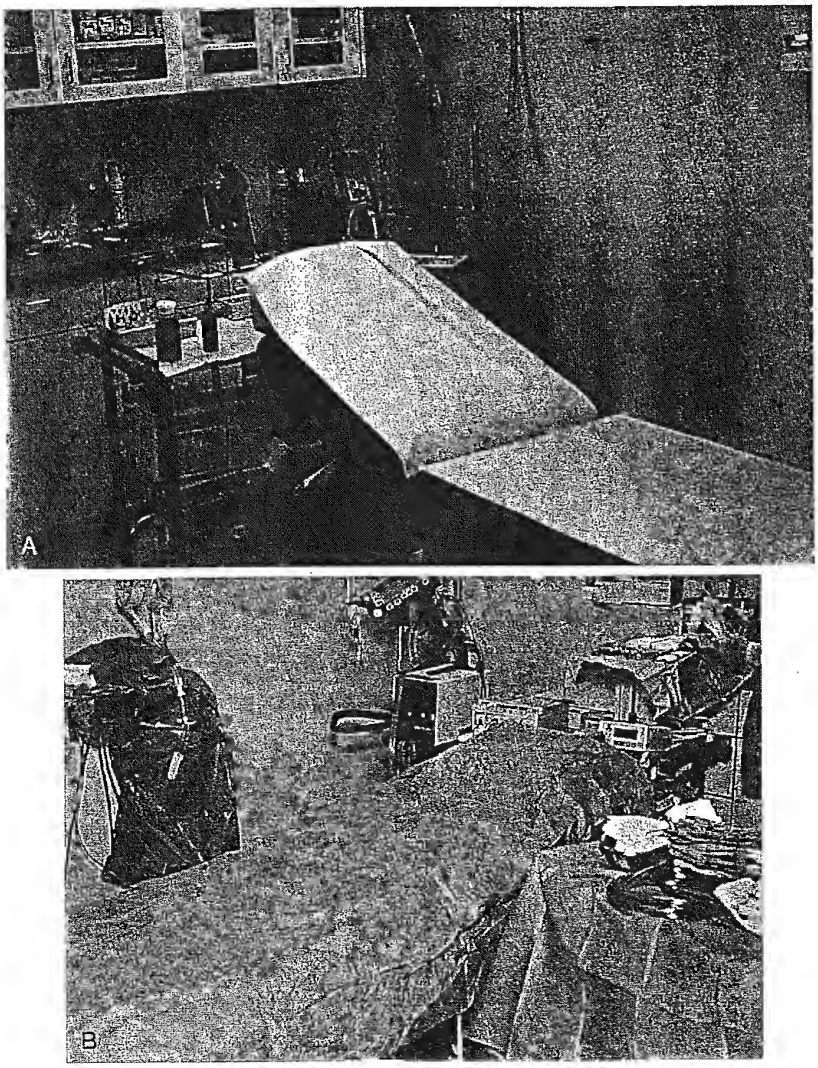

Figure 10. *A*, Operating table is placed in center of large operating room. Allows easy access to patient from all sides. *B*, Operating table covered with sterile waterproof cover. All operating surfaces covered with sterile drapes.

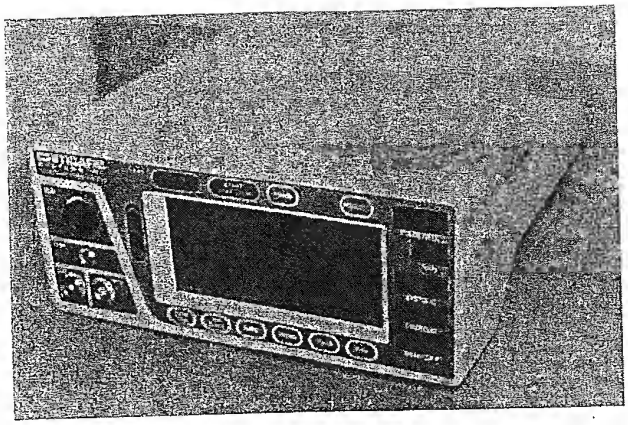

Figure 11. Multiple monitor appropriate for liposuction measures blood pressure, pulse, oxygen saturation, and echocardiogram. Body temperature monitor available as well.

space. Although many surgeons do not feel the need to regularly monitor healthy low-risk patients, the capability to do so should be available in case of an emergency.

ANCILLARY EQUIPMENT

In addition to the previously mentioned instruments and equipment, there are a variety of other instruments that should be considered to be useful and important in liposuction surgery. Because of the length of the procedure and the exposure of large surface areas of patient's skin, many surgeons prefer to have warming devices for their patients. As mentioned earlier, there is evidence that prolonged chilling stresses the heart and raises the risk of infection.[6,17] Impaired clotting function and prolonged healing from mild hypothermia have been reported as well.[22] The use of electric heating pads is discouraged because of the possibility of burns or electrical shorts. The POPP* bed warmer circulates warm distilled

*The POPP bed warmer was named after Dr. Jeffrey Popp, Omaha, Nebraska, who discovered this unit and recommended it's use. It is manufactured by Gaymar Co., Buffalo, NY.

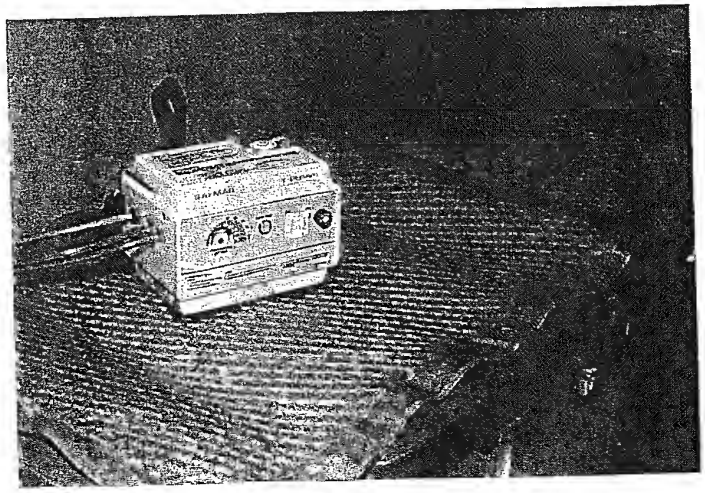

Figure 12. Bed warmer circulates warm water through rubberized blanket placed beneath the patient to maintain patient comfort and avoid lowering of body temperature.

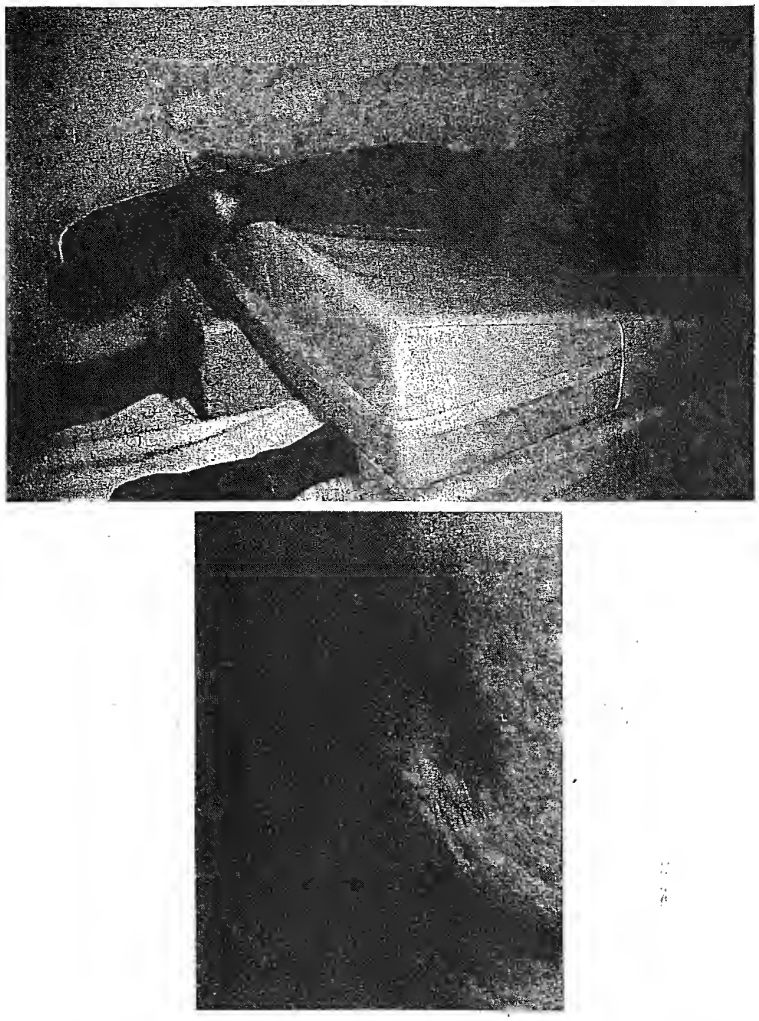

Figure 13. *A*, View of patient's leg on wedge demonstrating position during liposuction. *B*, Using this device, one can reduce the likelihood of forming a depression in the posttrochanteric space, as shown here.

water through a rubberized mat placed beneath the patient (Fig. 12). As the heating device is separated from the patient, there is no danger of electrical accidents. In addition, the upper limit to the temperature is 105°F, so there is no possibility of burning the patient. Most patients find this extremely comfortable, especially during long procedures. The heating pad is appropriately placed beneath the sterile waterproof table covers.

Another device, the leg wedge, is used to elevate the thigh during liposuction of the trochanteric or saddlebag area. When properly used, the foot extends beyond the wedge and is pointed downward, rotating the trochanter forward. This allows liposuction in an area of posttrochanteric depression that, if over-resected, will create a permanent indentation. The device usually has a smaller pad on which to rest the upper knee when performing liposuction of the medial thighs with the patient in the lateral decubitus position (Fig. 13).

POSTOPERATIVE GARMENTS

There are a variety of postoperative garments that are used for liposuction patients.

As many surgeons want their patients to wear these garments continuously for at least several days, appropriate openings are provided so that they may go to the bathroom without removing the garments. The garments are generally made with the zippers and snaps on the outside to avoid discomfort to the patient. Many styles of garments are available, which vary slightly in size, shape and degree of compressiveness. They are worn for as short a period as a few days to as long as a month or more. Some patients prefer to wear these garments even longer because they feel comfortable.

Some liposuction surgeons prefer the use of a compressive tape, which is applied in a herring bone or criss-cross fashion, either with or without the supplementary compressive garments. This too is a matter of professional preference. There is no evidence that this practice provides a better long-term cosmetic result.

Liposuction of the calves and ankles often results in long-lasting edema.[8, 19–21] In order to control postoperative edema, patients are advised to use fitted compressive hose, 30 to 40 mm Hg, which they will wear for prolonged periods. Although some surgeons recommend that these compressive stockings be worn continuously, others recommend use of 30 to 40 mm Hg during the day, when the patient is ambulatory, and to use only 18 mm Hg hose at night when the legs are somewhat elevated.[19, 21]

ULTRASOUND

Postoperative therapeutic ultrasound, usually at a frequency of 1 mH, has been used effectively to reduce edema, induration, and discomfort (Fig. 14). Many patients note significant improvement when this is applied during the early postoperative phase. Some therapists recommend that ultrasound not be used until 2 weeks postoperatively whereas others encourage its use in the very early postoperative inflammatory stage.[4] It is important that nurses and assistants applying the ultrasound be acquainted with the proper use and especially the risks of ultrasound. Many surgeons find that ultrasound is an in-

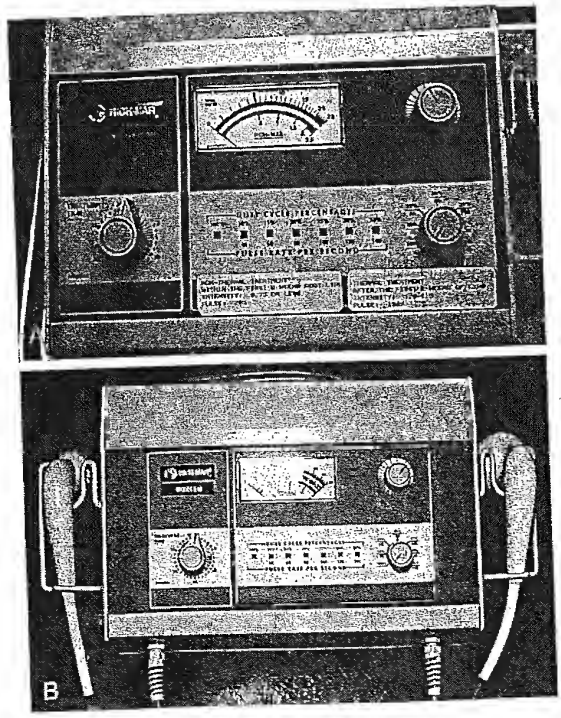

Figure 14. *A*, One- and *B*, three-watt ultrasonic generators that can be used for preoperative or postoperative liposuction.

valuable aid to the postoperative care of their patients.[1, 11]

CONCLUSION

Modern liposuction has been proven over the past two decades to be an extremely safe and effective technique for the removal of unwanted fatty deposits. Attention to proper surgical techniques plus the use of proven safe and effective instruments and equipment, will help ensure that the physician offers and that the patient receives the finest in surgical treatment. It is important that the equipment be frequently examined and well-maintained. We can look forward to further enhancements in instrumentation for this remarkable procedure in the coming decades.

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